UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: OPANA ER ANTITRUST LITIGATION WALGREEN CO., THE KROGER CO., SAFEWAY INC., HEB GROCERY COMPANY L.P. and ALBERTSON'S LLC, Plaintiffs, vs. ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS INC., PENWEST PHARMACEUTICALS CO., and IMPAX LABORATORIES INC., Defendants.	MDL DOCKET NO. 2580 Civil Action No._____ JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC bring this civil action against Defendants Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co. (collectively "Endo") and Impax Laboratories Inc. ("Impax") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful exclusion of generic competition to the brand-name drug Opana ER, an extended-release drug that contains as its active ingredient oxymorphone hydrochloride, marketed by Endo for the treatment of pain. Endo paid Impax more than $112 million in cash in exchange for Impax's agreement to delay the launch of its less expensive generic version of

Opana ER for two and a half years—from June 2010 to January 2013. Endo used that delay to switch the market from Opana ER to a new formulation of Opana ER—Opana ER crush resistant formulation ("Opana ER CRF"). But for Defendants' anticompetitive market allocation scheme, Impax would have launched its generic version of Opana ER as early as June 14, 2010 for the 5, 10, 20 and 40 mg strengths, and as early as July 22, 2010 for the 30 mg strength (the dates on which Impax received final FDA approval for those respective strengths), and the vast majority of those sales would have gone to Impax's less expensive generic. Defendants' scheme injured Plaintiffs by depriving them of the ability to substitute less expensive generic Opana ER for more expensive branded Opana ER and thereby caused them to pay millions of dollars in overcharges.

2. Oxymorphone hydrochloride has been marketed and sold by Endo in the United States for almost 50 years in various dosage forms. Oxymorphone hydrochloride was also available as a tablet during the 1960s and early 1970s. During the 1990s, Endo decided to revive the tablet formulation of oxymorphone hydrochloride. However, Endo knew that the longest period of (non-patent) exclusivity that Endo could obtain for the revived tablet formulation was three years. The original United States patent on oxymorphone hydrochloride itself was issued in the 1950s and expired many years ago.

3. Seeking to obtain a longer period of exclusivity, Endo Pharmaceuticals Inc. licensed four patents on time-release technology from Penwest Pharmaceuticals Co. ("Penwest") and developed extended release oxymorphone hydrochloride tablets, which Endo named Opana ER. Endo then embarked on a strategy to block generic competition to Opana ER beyond three years.

4. First, Endo sued generic manufacturers which sought to market generic Opana ER—including Impax, Actavis South Atlantic LLC ("Actavis"), Sandoz, Inc. ("Sandoz"), Barr Laboratories, Inc. ("Barr"), Roxane Laboratories, Inc. ("Roxane") and Watson Laboratories, Inc. ("Watson")—for purportedly infringing the licensed Penwest patents. Under the Hatch-Waxman Act (discussed below), the mere filing of these lawsuits prevented the FDA from approving the applications of these generic manufacturers for 30 months, regardless of the merit or outcome of the lawsuits.

5. Second, Endo ended its litigation with Impax (the first generic manufacturer to file an application for the vast majority of Opana ER sales) by entering into an agreement (the "Exclusion Payment Agreement") under which Impax agreed to keep its generic version of Opana ER off the market for two and a half years in exchange for a large future cash payment and other consideration. The Exclusion Payment Agreement contained three forms of payment from Endo to Impax: (a) a future cash payment based on sales of Opana ER in the quarter immediately prior to the delayed Impax launch date established in the agreement (a payment of $102,049,000 that was in fact made and received by Impax in April 2013); (b) Endo's agreement not to launch an "authorized generic" during Impax's first 180 days on the market with its generic extended release oxymorphone hydrochloride product; and (c) a cash payment of $10 million up front with an obligation to pay an additional $30 million later under the guise of a development and co-promotion agreement for Impax's yet-to-be-approved drug to treat Parkinson's disease.

6. Thus, in exchange for at least $142 million in cash and a promise by Endo not to compete with Impax during Impax's 180 days of exclusivity (a promise worth at least as much at the time it was made as the cash), Impax agreed not to compete with Endo's branded Opana ER

until January 2013—two and a half years after Impax received final FDA approval to sell generic versions of Opana ER.

7. Third, Endo ended its litigation with Actavis, Sandoz, Barr, Roxane and Watson and used the Exclusion Payment Agreement to create a bottleneck whereby no other generic manufacturer could sell a generic version of Opana ER until Impax had been on the market for 180 days selling generic versions of Opana ER in the 5, 10, 20, 30 and 40 mg strengths (without competition from an authorized generic).

8. Endo then used the delay it had purchased from Impax to switch the market from Opana ER to Opana ER CRF—a purportedly crush-resistant version of Opana ER that is otherwise medically and therapeutically equivalent to Opana ER. Beginning in 2012, long after the vast majority of branded Opana ER sales would have been replaced with sales of the less expensive generic but for Defendants' unlawful conduct, Endo launched Opana ER CRF and set about converting all Opana ER prescriptions to prescriptions for Opana ER CRF. Thus, by the time Impax belatedly launched its generic version of Opana ER in January 2013, the market for that original version of Opana ER had substantially shrunk and, because generic versions of Opana ER are not substitutable for branded Opana ER CRF at the pharmacy counter, Impax made far fewer sales of its generic than it would otherwise have made and Plaintiffs made far fewer purchases of the generic than they otherwise would have made. Apparently anticipating Endo's plan to switch the market, Impax ensured that if sales of Opana ER fell below a predetermined contractual floor in the quarter immediately prior to January 1, 2013, Impax would receive a cash payment from Endo that grew larger in proportion to the amount by which Opana ER's sales fell below the predetermined floor. In this way, Impax made sure that it would be well compensated for not competing with Endo even if Endo were able to switch the market

successfully from Opana ER to Opana ER CFR (as Endo in fact did) and thereby reduce the generic sales that Impax would ultimately make.

9. But for Endo's large and unlawful reverse payment to Impax, Impax would have launched generic Opana ER years earlier than it actually did, either (a) at risk (while the patent litigation was still pending); (b) after winning the patent litigation; or (c) via a lawful entry-date-only settlement agreement that did not include a large reverse payment. By entering into the Exclusion Payment Agreement, Endo and Impax agreed to allocate virtually all of the market for Opana ER and its generic equivalents to Endo during the period from June 2010 to January 2013, and also to allocate the market for generic Opana ER to Impax during the first six months of 2013.

10. Defendants' Exclusion Payment Agreement was designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of Opana ER; (b) fix, raise, maintain and stabilize the price of Opana ER and AB-rated generic versions of Opana ER; (c) allocate nearly 100% of the United States market for Opana ER and its AB-rated generic equivalents to Endo for at least two and a half years; and (d) allocate nearly 100% of the United States market for generic Opana ER to Impax for the first six months of 2013.

11. Plaintiffs are direct purchasers or assignees of direct purchasers of Opana ER and are included in the proposed class definition in actions currently pending in this Court as part of *In re Opana ER Antitrust Litigation*, MDL Docket No. 2580. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first class action on behalf of direct purchasers of Opana ER.

II. THE PARTIES

12. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates

retail stores in several states at which it dispenses prescription drugs, including Opana ER, to the public. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased Opana ER directly from Endo for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen. In addition, Walgreen is contractually entitled to a second assignment from AmerisourceBergen Drug Corporation ("ABDC"), another pharmaceutical wholesaler, which during the relevant period purchased Opana ER directly from Endo for resale to Walgreen. Walgreen intends to include purchases made through ABDC in its damage claim upon receipt of that assignment.

13. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Opana ER, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Opana ER directly from Endo for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

14. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs, including Opana ER, to the public. Safeway brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Opana ER directly from Endo for resale to Safeway and which has assigned its claim arising out of those purchases to Safeway.

15. Plaintiff HEB Grocery Company L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204.

HEB owns and operates retail stores at which it dispenses prescription drugs, including Opana ER, to the public. HEB brings this action in its own behalf and as the assignee of Cardinal and McKesson Corporation ("McKesson"), another pharmaceutical wholesaler, which during the relevant period purchased Opana ER directly from Endo for resale to HEB and which have assigned their claims arising out of those purchases to HEB.

16. Plaintiff Albertson's LLC ("Albertson's") is a Delaware limited liability company having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertson's owns and operates retail stores in several states at which it dispenses prescription drugs, including Opana ER, to the public. Albertson's brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Opana ER directly from Endo for resale to Albertson's and which has assigned a portion of its claims arising out of those purchases to Albertson's.

17. Defendant Endo Health Solutions Inc. is a Delaware corporation having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Until May 2012, Endo Health Solutions Inc. was known as Endo Pharmaceutical Holdings Inc.

18. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc.

19. Defendant Penwest Pharmaceuticals Co. was acquired by Endo Pharmaceutical Holdings Inc. on November 4, 2010. Prior to that date, Penwest was a Washington corporation. Penwest was previously known as Edward Mendell Co.

20. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax

develops, manufactures and markets pharmaceutical products, primarily generic products, in the United States.

21. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

22. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful suppression of competition in the United States market for extended-release oxymorphone hydrochloride. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

23. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c) and 28 U.S.C. § 1407(a).

IV. OPERATIVE FACTS

A. Characteristics of the Prescription Pharmaceutical Marketplace

24. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation

and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

25. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Opana ER, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

26. Endo and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

27. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market

imperfections and marketing practices described above is to allow manufacturers of branded prescription pharmaceutical products to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

28. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

29. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

30. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

31. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

32. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

33. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

34. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

35. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

36. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30-months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA

may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

37. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

38. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30-months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the

generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

39. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

40. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30-months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30-months.

41. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that

qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

42. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provision and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

E. The Benefits of Generic Drugs

43. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus

usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. At retail pharmacy chains like Plaintiffs, generic substitution typically reaches 90% in 90 days. As a result, competition from generic drugs is viewed by brand name drug companies such as Endo as a grave threat to their bottom lines.

44. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

45. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retail pharmacies pay less to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that generic competition brings.

46. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the conduct at issue here.

F. The Impact of Authorized Generics

47. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product either by the brand manufacturer or through a third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

48. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

49. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as Plaintiffs benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

50. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from

the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

51. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

V. DEFENDANTS' ANTICOMPETITIVE SCHEME

A. Endo Revives Tablet Formulations of Oxymorphone Hydrochloride and Acquires Time Release Patents from Penwest

52. Oxymorphone hydrochloride is a strong opioid agonist used to treat pain and also as a preoperative medication to alleviate apprehension, maintain anesthesia, and as an obstetric analgesic. Oxymorphone hydrochloride was first synthesized in 1914.

53. Endo has sold oxymorphone hydrochloride in the United States for almost 50 years. The FDA approved Endo's NDA for injectable oxymorphone hydrochloride in 1959. In 1960, the FDA approved Endo's NDA for a rectal suppository form of oxymorphone hydrochloride. Endo marketed the latter under the brand name Numorphan. In the 1960s, oxymorphone hydrochloride was also made available in an oral immediate release tablet, but that formulation was withdrawn from the market in 1972. Endo continued to market Numorphan in injectable and rectal suppository formulations, but these were used relatively infrequently.

54. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo was aware that the original patent on oxymorphone hydrochloride, issued in 1957, had expired, and because oxymorphone hydrochloride was a previously approved molecule, it would not be eligible for the five years of regulatory exclusivity awarded to approval of new chemical entities. Instead, Endo would be eligible for at most three years of regulatory exclusivity if Endo submitted new clinical studies in support of its NDA.

55. Upon information and belief, not satisfied with the prospect of only three years of regulatory exclusivity, Endo Pharmaceuticals Inc. purchased from Penwest the rights to patents that it could use to block generic entry beyond those three years. As such, on September 17, 1997, Endo Pharmaceuticals Inc. entered into a collaboration agreement with Penwest to exclusively co-develop opioid analgesic products using Penwest's patents. Penwest possessed several patents related to time release formulations for drug tablets (as opposed to patents on the drug molecules themselves, known as "compound patents"). In the 1990s, Penwest (then known as Edward Mendell Co.) obtained four patents all related to time release formulations. These included United States Patent No. 5,128,143 (the "'143 patent"), United States Patent No. 5,958,456 (the "'456 patent") and United States Patent No. 5,662,933 (the "'933 patent"). In 2002, Penwest also filed an application for what ultimately issued as United States Patent No. 7,276,250 (the "'250 patent"). The '143, '456, '933, and '250 patents are collectively referred to as the "Penwest time release patents."

56. Penwest then licensed the Penwest time release patents to Endo Pharmaceuticals Inc.

57. Opana ER is an extended release ("ER") form of oxymorphone hydrochloride indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

58. Opana IR is an immediate release ("IR") form of oxymorphone hydrochloride indicated for the relief of moderate to severe acute pain.

59. Endo began selling Opana ER and Opana IR on or about July 21, 2006. Opana ER was originally approved and marketed in 5, 10, 20, and 40 mg tablets, and Opana IR was approved and marketed in 5 and 10 mg tablets.

60. In March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg tablets. Endo began selling those strengths of Opana ER on or about April 1, 2008.

61. As a result of having conducted new clinical studies, Endo was awarded three years of regulatory exclusivity for all strengths of Opana ER and all strengths of Opana IR, preventing the FDA from approving any ANDAs for either drug through June 22, 2009, after which Endo's Opana ER and Opana IR monopolies would be subject to generic competition.

62. The lower strengths of Opana ER (5, 7.5, 10, and 15 mg) are typically used to gradually taper patients on and off Opana ER. The higher strengths (20, 30, and 40 mg) are typically used for the treatment of pain and account for the great majority of Opana ER sales. For example, for the period from January 2009 to March 2011, total sales of Opana ER were just over $757 million, but sales of the 7.5 and 15 mg strengths were only $37.8 million, or 5% of total sales, whereas sales of the 20, 30, and 40 mg strengths were $642.8 million, representing 85% of total sales.

1. Opana IR's new clinical study exclusivity expires and generic competition for Opana IR begins

63. Although Opana ER and Opana IR share the same active ingredient, Endo did not have any patents available to assert in order to extend its Opana IR monopoly beyond the three-year new-clinical-study exclusivity. Thus, Opana IR's exclusivity expired on June 22, 2009, and the normal process of generic entry (including Endo launching an authorized generic) occurred.

64. Following the expiration of Opana IR's exclusivity, generic manufacturers entered the market and drove the price of immediate release oxymorphone hydrochloride down to competitive levels.

65. Roxane was the first-filer for Opana IR 5 and 10 mg tablets. Roxane's ANDA was approved on September 27, 2010, and Roxane began selling generic immediate release oxymorphone hydrochloride 5 and 10 mg tablets on or about that day.

66. On or about November 1, 2010, Endo began selling 5 and 10 mg Opana IR tablets as authorized generics.

67. Teva Pharmaceuticals USA, Inc. ("Teva") was the second generic company to file an ANDA for 5 and 10 mg Opana IR tablets. The FDA approved Teva's ANDA on February 15, 2011, and Teva began selling generic immediate release oxymorphone hydrochloride 5 and 10 mg tablets soon thereafter. Avanthi, Inc. ("Avanthi") was the third generic company to file an ANDA for 5 and 10 mg Opana IR tablets. Avanthi's ANDA was approved on January 30, 2013, and Avanthi launched thereafter through Avanthi's United States agent KVK-Tech, Inc.

68. But for the anticompetitive Exclusion Payment Agreement, generic competition for Opana ER would have commenced in a similar way in June 2010 and would have driven the price for extended release oxymorphone hydrochloride down to competitive levels.

2. Endo leverages Penwest's time release patents to extend Endo's monopoly on OpanaER

69. As noted above, Penwest licensed the '143, '250, '456, and '933 patents to Endo Pharmaceuticals Inc. At the time of launch in 2006, however, Endo listed only the '143 patent in the Orange Book as covering Opana ER. The '143 patent was set to expire in 2008 before the expiration of Endo's three-year exclusivity on June 22, 2009, and thus offered no relevant protection from generic competition.

70. The '456, and '933 patents were not listed in the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53.

71. Pursuant to 21 C.F.R. § 314.53, brand companies must declare all patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" for listing in the Orange Book within 30 days of filing an NDA. Late listing means listing a patent in the Orange Book more than 30 days after an NDA is approved in violation of 21 C.F.R. § 314.53.

72. Recognizing that generics would soon submit ANDAs that could be approved in time to allow for the sale of generic Opana ER as soon as Endo's three-year clinical study exclusivity expired on June 22, 2009, in October 2007, over a year after Opana ER was launched, Endo late listed three additional Penwest time release patents – the '250, '456, and '933 patents – in the Orange Book.

3. Endo sues lmpax triggering a 30-month Hatch-Waxman Stay

73. As Endo expected, on or about June 29, 2007, Impax filed ANDA 79-087 for its generic extended release oxymorphone hydrochloride. Although the FDA initially accepted

Impax's June 29, 2007 ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies.

74. In or before November 2007, Impax resubmitted ANDA 79-087 to the FDA (rectifying the previous deficiencies) and included a Paragraph IV certification stating that Impax's proposed generic extended release oxymorphone hydrochloride tablets in 5, 10, 20, and 40 mg strengths did not infringe the '250, '456, or '933 patents.

75. On December 12, 2007, the FDA advised Impax that its ANDA 79-087 "has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007."

76. On December 13, 2007, Impax sent Endo a notice stating that it had submitted ANDA 79-807 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The December 13, 2007 notice also advised Endo that Impax's ANDA 79-087 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release oxymorphone hydrochloride tablets described in Impax's ANDA 79-087 would not infringe any claim of the '250, '456, or '933 patents.

77. On January 25, 2008, Endo sued Impax in the United States District Court for the District of Delaware for alleged infringement of the '456 and '933 patents, but did not allege infringement of the '250 patent. Merely by filing this suit (and regardless of its merit or lack thereof), Endo triggered the automatic 30-month Hatch-Waxman stay, through mid-June 2010, during which time the FDA could not approve Impax's ANDA 79-087 for 5, 10, 20, and 40 mg generic Opana ER.

78. Impax was the first generic company to file an ANDA with a Paragraph IV certification as against the '250, '456, and '933 patents for the 5, 10, 20, and 40 mg strengths of

Opana ER. This meant that Impax, as first filer, was entitled to 180 days of exclusivity for those strengths as against other ANDA filers. By delaying Impax's entry into the market, Endo could therefore delay all generics from entering the market for the 5, 10, 20, and 40 mg strengths of Opana ER.

79. With the Impax patent litigation pending, in March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg. Endo launched these strengths of Opana ER on or about April 1, 2008.

80. Soon thereafter, on June 13, 2008, Impax sent Endo a notice stating that Impax had filed an amendment to ANDA 79-087 to include the 7.5, 15, and 30 mg strengths. The June 13, 2008 notice also advised Endo that Impax's amended ANDA included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release oxymorphone hydrochloride tablets described in its ANDA would not infringe any claim of the '250, '456, or '933 patents.

81. Impax was the first Paragraph IV filer against the '250, '456, and '933 patents for the 30 mg strength of Opana ER. As a result, Impax was entitled to 180 days of marketing exclusivity for the 30 mg strength of generic Opana ER (as discussed below, Actavis was the first-filer for the 7.5 and 15 mg strengths of generic Opana ER).

82. On July 25, 2008, Endo filed another lawsuit against Impax in the United States District Court for the District of Delaware alleging that Impax's amendment to its ANDA covering the 7.5, 15, and 30 mg tablets of generic Opana ER infringed the '456 and '933 patents (but not the '250 patent).

83. In February 2009, the lawsuits that Endo filed against Impax relating to Opana ER were consolidated and transferred to the United States District Court for the District of New Jersey under the lead docket number 09-831 (the "Impax Patent Litigation").

4. Endo sues other generic manufacturers who submit ANDAs for Opana ER

84. Endo sued subsequent generic ANDA filers for extended release oxymorphone hydrochloride.

a. Actavis

85. In February 2008, Endo received a notice from Actavis stating that Actavis had submitted ANDA 79-046 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The Actavis notice advised Endo that Actavis' ANDA 79-046 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release oxymorphone hydrochloride tablets described in Actavis' ANDA would not infringe any claim of the '250, '456, or '933 patents and that the claims in those patents are invalid.

86. On March 28, 2008, Endo sued Actavis in the United States District Court for the District of New Jersey alleging infringement of only the '456 patent (it did not sue on the '250 or '933 patents). By filing this suit, Endo triggered the automatic 30-month stay during which the FDA could not approve Actavis' ANDA for 5, 10, 20, and 40 mg generic Opana ER until August 2010 at the earliest.

87. On or about May 29, 2008 (covering 7.5 and 15 mg Opana ER) and June 30, 2008 (covering 30 mg Opana ER), Actavis sent Paragraph IV notices to Endo informing it that Actavis had amended its ANDA to include the new dosage strengths of Opana ER and that the Actavis

generic Opana ER would not infringe the '250, '456, or '933 patents and that the claims in those patents are invalid.

88. Actavis was the first generic company to file a Paragraph IV certification with respect to the patents that Endo listed in the Orange Book for the 7.5 and 15 mg strengths of Opana ER and Actavis was therefore entitled to 180 days of market exclusivity upon final FDA approval as against other ANDA filers (as discussed above, Impax was the first-filer for all other dosage strengths). The 7.5 and 15 mg strengths, however, are used primarily to taper patients on and off the drug and constitute a small part of all Opana ER sales.

89. On July 11, 2008, Endo filed a second suit against Actavis in the United States District Court for the District of New Jersey alleging infringement of the '456 patent only (but not the '250 or '933 patents), triggering the 30-month Hatch-Waxman automatic stay with regard to the 7.5, 15, and 30 mg strengths of Actavis' generic Opana ER.

90. The Actavis suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 08-1563 (the "Actavis Patent Litigation").

b. Sandoz

91. On or about July 9, 2008, Sandoz sent a Paragraph IV notice to Endo with regard to Sandoz's ANDA 90-565 covering generic Opana ER in 5, 10, 20, and 40 mg dosage strengths explaining that the Sandoz generic would not infringe the '250, '456 or '933 patents.

92. On August 22, 2008, Endo sued Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent only (but not the '250 or '933 patents), triggering the 30-month Hatch-Waxman stay.

93. On or about November 17, 2008, by way of Paragraph IV notice and again explaining that its generic Opana ER does not infringe the '250, '456 or '933 patents, Sandoz informed Endo that it had amended its ANDA to include 7.5, 15 and 30 mg strengths of generic OpanaER.

94. On or about December 30, 2008, Endo filed a second suit against Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent (but not the '250 or '933 patents) for 7.5, 15 and 30 mg strengths of generic Opana ER, again triggering the 30-month Hatch-Waxman stay.

95. The two Sandoz suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-836 (the "Sandoz Patent Litigation").

c. Barr

96. On or about September 11, 2008 (40 mg tablets) and September 12, 2008 (5, 10 and 20 mg tablets), Barr sent Endo Paragraph IV notices with respect to Barr's generic Opana ER ANDA 90-106 asserting that Barr's generic products would not infringe the '250, '456 or '933 patents or the patents were invalid or not enforceable.

97. On October 20, 2008, Endo sued Barr in the United States District Court for the District of Delaware alleging that Barr's ANDA product would infringe the '456 and '933 patents (but not the '250 patent), triggering the 30-month Hatch-Waxman stay.

98. On or about June 1, 2009, Endo received another Paragraph IV notice from Barr covering the 7.5, 15, and 30 mg strengths of generic Opana ER.

99. Soon thereafter, on July 2, 2009, Endo filed another suit against Barr in the United States District Court for the District of New Jersey alleging infringement of only the '456 and

‘933 patents (but not the ‘250 patent), again triggering the 30-month Hatch-Waxman stay for the 7.5, 15, and 30 mg strengths of Barr’s generic Opana ER.

100. The two Barr suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-838 (the “Barr Patent Litigation”).

d. Roxane

101. On or about December 28, 2009, Roxane sent Endo a Paragraph IV notice with respect to Roxane’s ANDA 20-0822 for generic Opana ER in a 40 mg dosage strength explaining that the Roxane generic would not infringe the ‘250, ‘456 or ‘933 patents.

102. On or about January 29, 2010, Endo filed a lawsuit against Roxane in the United States District Court for the District of New Jersey alleging infringement of only the ‘456 patent (but not the ‘933 or ‘250 patents), triggering the 30-month Hatch-Waxman stay.

103. On or about March 18, 2010, Roxanne sent a second Paragraph IV notice to Endo (covering generic Opana ER in the 7.5, 10, 15, 20 and 30 mg strengths) and again asserting that the Roxane generic product would not infringe the ‘250, ‘456 or ‘933 patents.

104. On or about April 16, 2010, Endo again sued Roxanne, alleging infringement of the ‘456 patent (but not the ‘933 or ‘250 patents), triggering the 30-month Hatch-Waxman stay.

105. The Roxane suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 10-534 (the “Roxane Patent Litigation”).

e. Watson

106. On or about January 19, 2010, Endo received a Paragraph IV notice from Watson advising that Watson's ANDA 20-0792 for generic Opana ER in a 40 mg dosage strength would not infringe the '250, '456 or '933 patents.

107. On or about March 4, 2010, Endo sued Watson in the United States District Court for the District of New Jersey alleging infringement of the '456 and '933 patents (but not the '250 patent), triggering the 30-month Hatch-Waxman stay.

108. On or about March 18, 2010, Watson sent a Paragraph IV notice regarding its ANDA for generic Opana ER in 5, 7.5, 10, 15, 20, and 30 mg dosage strengths.

109. On April 23, 2010, Endo amended the Watson complaint to include infringement allegations regarding the additional dosage strengths and therefore triggered the 30-month Hatch-Waxman stay with regard to the 5, 7.5, 10, 15, 20, and 30 mg strengths as well.

B. Endo and Impax Enter the Exclusion Payment Agreement

1. Endo and Impax enter the Exclusion Payment Agreement during the Impax Patent Litigation and after FDA's tentative approval of Impax's ANDA

110. From 2007 to 2010, during the 30-month stay period, Endo and Impax litigated their patent infringement suit in the United States District Court for the District of Delaware and then, following transfer and consolidation of the Impax patent cases, in the United States District Court for the District of New Jersey. The Impax Patent Litigation was consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.

111. The case proceeded through discovery and claim construction briefing. The Honorable Katherine S. Hayden of the United States District Court for the District of New Jersey conducted a *Markman* hearing on December 21, 2009 and March 19, 2010. Judge Hayden then entered an order on claim construction on March 30, 2010.

112. In a March 8, 2010 Final Pretrial Order, Impax asserted that it would prove that the '456 and '933 patents were invalid because they were: (1) anticipated by prior art; (2) obvious; (3) and constituted obvious-type double patenting. Further, Impax intended to prove that the '933 patent lacked an adequate written description. Finally, Impax contended that its generic Opana ER did not infringe the '250, '456, and '933 patents even if those patents were valid.

113. As noted above, the 30-month stay on Impax's ANDA 79-046 was set to expire (and did expire) on or about June 14, 2010.

114. On May 4, 2010, Impax held its first quarter 2010 earnings call. During that call, Impax's then-President and CEO indicated that lmpax was expecting to receive tentative approval of its generic Opana ER ANDA 79-046 by May 23, 2010, and that Impax was preparing to launch generic Opana ER.

115. On May 13, 2010, the FDA tentatively approved Impax's ANDA 79-046 for all dosage strengths of Opana ER; final approval of Impax's generic Opana ER had to wait for the running of the 30-month Hatch-Waxman stay on June 14, 2010.

116. The next day, May 14, 2010, during a telephonic hearing to discuss Endo's desire to file a preliminary injunction motion to extend the statutory stay of FDA approval of Impax's proposed generic tablets, counsel for Endo represented that Endo had "indications" that Impax was "actually going down that road" of making and stockpiling generic Opana ER product (*i.e.*, Endo understood that Impax was preparing to launch at risk). In response, counsel for Impax represented that Impax "certainly . . . will have the right to launch the [Opana ER generic] product upon final approval in mid-June." Counsel for Impax further represented that, "I

certainly today could not say that we would agree not to launch on June 14th. It is our statutory right to launch the product after final approval."

117. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3, 2010 and to conclude by June 17, 2010 (only three days after the 30-month stay was to end and Impax could receive final approval), and to avoid distractions caused by briefing the preliminary injunction motion seeking to extend the statutory stay of FDA approval of Impax's proposed generic tablets filed by Endo, Impax agreed it would "not launch its ANDA product (generic oxymorphone [hydrochloride] extended-release tablets) through and including the last trial day as presently scheduled" in a May 20, 2010 letter to Judge Hayden.

118. The bench trial commenced on June 3, 2010 and continued on June 7, 2010.

119. Endo was aware that its patents and its patent infringement claims against Impax were weak and that it would not be able to obtain an injunction to stop Impax from launching its generic versions of Opana ER after Impax obtained final approval from the FDA. Likewise, Impax knew that it could make as much or more money by agreeing not to compete with Endo than by actually launching its generic Opana ER product. Had Impax launched generic versions of Opana ER upon receiving FDA final approval for its 5, 10, 20, and 40 mg strengths on June 14, 2010 (representing the vast majority of Opana ER sales) or at the conclusion of the trial, as it was preparing and poised to do prior to the Exclusion Payment Agreement, Impax's generics would have rapidly driven down the price of extended release oxymorphone hydrochloride tablets. Impax was further aware that once its 180-day exclusivity period ran and there were multiple generic versions of Opana ER available, the generics would become a commodity, with little or nothing to distinguish one generic from another except price. Impax was well aware of these market dynamics, and knew that it could likely make as much or even more money by

agreeing to withhold its generic products in favor of, in effect, splitting Endo's monopoly profits from Opana ER, and that is precisely what happened.

120. With the bench trial underway, Endo, Penwest (which had not yet been acquired by Endo) and Impax settled the Impax Patent Litigation by simultaneously entering into the Impax Settlement Agreement and the Impax Development Agreement (together the "Exclusion Payment Agreement") on or about June 8, 2010. The bench trial transcripts were sealed, and on June 15, 2010 the Impax Patent Litigation was dismissed with prejudice.

2. Impax agrees to delay launching generic Opana ER for two and a half years in exchange for a future cash payment of over $102 million and other consideration from Endo

121. In exchange for a future cash payment of more than $102 million as well as other consideration from Endo, Impax agreed to delay the launch of its generic Opana ER products from June 14, 2010 to January 1, 2013, and to refrain from challenging the validity or enforceability of the '933 and '456 patents as well as the '250 patent, which Endo did not even accuse Impax of infringing. Pursuant to the Exclusion Payment Agreement, Endo granted Impax a license and covenant not to sue for infringement of the '250, '456, and '933 patents as well as any continuations of those patents and to any pending patent applications relating to Opana ER.

122. As a *quid pro quo* for Impax's agreement to delay the entry of generic Opana ER and refrain from challenging Endo's patents, Endo compensated Impax handsomely. In addition to Endo's grant of a license to Impax for the Penwest time release patents that Impax asserted it was not infringing, the Exclusion Payment Agreement provided several forms of large and unexplained payments from Endo to Impax to compensate Impax for its agreement to delay launching its generic.

123. First, the Exclusion Payment Agreement provided for a future cash payment from Endo to Impax if sales of Opana ER fell below a predetermined contractual threshold in the

quarter immediately prior to January 1, 2013. This payment in the amount of $102,049,000 was received by Impax in April 2013, and was far above any litigation costs saved by Endo (or Impax) by settling.

124. Second, the Exclusion Payment Agreement provided that Endo would withhold launch of an authorized generic ("AG") during Impax's 180-day exclusivity period, which at the time of the agreement was worth many millions of dollars to Impax—also well above any litigation costs saved by Endo (or Impax) by settling. Endo's agreement not to launch an AG meant that Impax would be the sole generic on the market for at least 180 days, and Impax could therefore not only obtain all generic sales but could do so at higher, supracompetitive prices, all at the expense of Plaintiffs and other purchasers of the drug. Absent the unlawful Exclusion Payment Agreement, it would have made economic sense for Endo to launch an AG during Impax's 180-day exclusive marketing period so that Endo could retain some of the sales that Impax's less expensive generic otherwise would capture. Endo would have expected its AG to capture approximately 50% of the generic sales during the first 180 days of generic marketing.

125. Third, the payment included a development and co-promotion agreement whereby Endo paid Impax $10 million in cash up front with an obligation to pay an additional $30 million, ostensibly for certain rights related to Impax's as-yet-unapproved next generation Parkinson's disease product.

126. To date, Impax has received at least $112,049,000 in cash (the payment of $102,049,000 explicitly compensating Impax for delaying entry plus an additional $10 million in cash up front as part of the purported Parkinson's drug agreement), and a "no-AG" agreement with a cash value to Impax of many millions of dollars, all in exchange for Impax's agreement to keep its generic Opana ER off the market for two and a half years.

127. Defendants have no procompetitive explanation or justification for the payments. This large, unjustified reverse payment had no rational connection to, and far exceeds, any approximation of the costs of continuing the patent litigation that was in the middle of trial at the time the agreement was signed. Nor was the payment consideration for the value of any goods or services provided by Impax to Endo. Other than delaying the launch of its generic Opana ER, Impax was not required to perform any service at all in exchange for the more than $102 million cash payment. Impax was also not required to perform any service for the additional $10 million upfront cash payment that was purportedly related to Impax's unapproved drug product. Endo simply paid Impax not to compete.

128. Absent Endo's unlawful payments to Impax under the Exclusion Payment Agreement, Endo and Impax would have settled in a manner less restrictive of competition, resulting in much less delay of Impax's generic entry than as happened pursuant to a settlement with unlawful payments. Under such an agreement, or even without one (such as with an at-risk launch by Impax, or launch after a court ruling in Impax's favor), Impax would have launched its generic Opana ER substantially earlier than 2013.

129. The likely reason that the future cash payment (the more than $102 million cash payment from Endo to Impax) called for by the Exclusion Payment Agreement was linked to the sales of Opana ER in the quarter immediately prior to Impax's launch was that Impax was concerned that Endo would switch the market in the interim.

130. In other words, Impax feared that, while it stayed out of the market for two and a half years, Endo would use this period to switch prescriptions and sales from branded Opana ER to some other brand formulation to which Impax's generic would not be AB-rated (and therefore not substitutable at the pharmacy counter). If Endo successfully implemented such a switch

before Impax launched its generic, Impax's ability to sell its generic would be greatly impaired, and Impax would make significantly fewer sales than it would have made if it entered after final approval in June 2010 because Impax's generic Opana ER would not be AB-rated to the new brand formulation. Hence, in the Exclusion Payment Agreement, Impax made sure that the large reverse payment to Impax was triggered by brand Opana ER sales falling below a certain threshold in the quarter immediately before the delayed launch date (January 2013) that Impax had agreed to in the Exclusion Payment Agreement. In short, Impax made sure that it would be well paid for staying off the market no matter what happened during the two and a half years of delay.

131. And, if Endo did not successfully switch the market to a new formulation (or did not try to do so), then the monetary value of Endo's promise not to compete with an AG would be much greater, as the sales of brand Opana ER would have remained stable or grown while Impax agreed not to enter the market, and without competition from Endo's AG, Impax could expect to sell its generic at supracompetitive prices and obtain more than twice as much revenue from selling its generic during its first 180 days than it would had it faced AG competition.

132. On June 14, 2010, just days after the parties entered into the Exclusion Payment Agreement, Impax received final approval for 5, 10, 20, and 40 mg strengths of generic Opana ER (representing the vast majority of Opana ER sales). On July 22, 2010, Impax received final approval for its 30 mg strength. But, because of the Exclusion Payment Agreement, Impax did not launch until two and a half years later, on January 4, 2013.

133. And, indeed, Endo ultimately did undertake efforts to switch the market from Opana ER to a new formulation of Opana ER called Opana ER CRF that was purportedly crush resistant. As a result, Impax received a reverse cash payment of more than $102 million.

3. Effects of the Exclusion Payment Agreement

134. The Exclusion Payment Agreement enabled Endo and Impax to (a) delay entry of less expensive generic versions of Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States, (b) fix, raise, maintain or stabilize the price of 5, 10, 20, 30, and 40 mg strengths of Opana ER and its generic equivalents, (c) permit Endo to maintain a monopoly in the United States market for Opana ER and its generic equivalents, (d) allocate the market for Opana ER and its generic equivalents almost exclusively to Endo through January 2013, and (e) allocate the market for generic Opana ER almost exclusively to Impax during the first six months of 2013.

135. The Exclusion Payment Agreement had the effect of delaying competition for 5, 10, 20, 30, and 40 mg oxymorphone hydrochloride extended release tablets for two and a half years. But for this reverse payment agreement, Impax would have begun marketing and selling its generic Opana ER as early as June 14, 2010 for the 5, 10, 20, and 40 mg strengths, and July 22, 2010 for the 30 mg strength, which are the dates on which Impax obtained final FDA approval of these strengths of generic Opana ER. Further, but for the no AG provision in the Exclusion Payment Agreement, when Impax did come on the market, Endo would have launched an AG to compete with Impax's generic Opana ER product, pushing generic prices lower.

136. Instead, as a result of the Exclusion Payment Agreement, Impax did not launch its 5, 10, 20, 30, and 40 mg generic Opana ER tablets until January 4, 2013, and, as promised, Endo did not launch a competing AG during Impax's 180-day exclusivity period. Thus, Impax was paid both in cash and through the "no AG" agreement to withhold its generic versions of Opana ER for two and a half years.

137. In addition, Endo and Impax, the first generic filer for the 5, 10, 20, 30, and 40 mg strengths of generic Opana ER tablets, also knew and intended that their Exclusion Payment

Agreement would prevent other generic companies from launching their own generic products in those strengths.

138. As the first-filer of an ANDA with a Paragraph IV certification for generic Opana ER for 5, 10, 20, 30, and 40 mg strengths, Impax was entitled to market its generic Opana ER in those strengths for 180 days free from competition from other generic Opana ER tablets (other than an AG) at those strengths. The operation of the Exclusion Payment Agreement between Endo and Impax thus effectively blocked any other generic Opana ER tablets in those strengths from coming to market until 180 days after January 4, 2013, because the FDA will not approve subsequently-filed ANDAs until the first-filer's exclusivity period has run. Endo admitted this in its Annual Report: "We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of generic non-tamper resistant Opana ER commencing on July 1, 2013 [i.e., 180 days after the Impax launch]."

139. In other words, Impax served as a "cork in the bottle." So long as there was not a court ruling invalidating the '456 and '933 patents (which would trigger the running of Impax's 180-day exclusivity period) the delayed launch of the Impax generic called for under the Exclusion Payment Agreement prevented any generic other than Impax from entering the market until July 2013 in the relevant strengths.

140. Thus, Defendants' Exclusion Payment Agreement delayed or prevented the sale of generic Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States for more than two and a half years, and unlawfully enabled Endo to sell Opana ER 5, 10, 20, 30, and 40 mg strengths at artificially inflated, supracompetitive prices.

141. If Impax had launched generic Opana ER in June and July 2010, the market for Opana ER would not have been substantially eroded by Endo's switch to Opana ER CRF, and

Impax would have made far more sales. Moreover, the Exclusion Payment Agreement prevented other generic manufacturers from launching additional generic versions of Opana ER beginning in or about December 2010, when Impax's 180-day exclusivity would have expired absent the Exclusion Payment Agreement.

C. Endo Settles the Actavis, Barr, Sandoz, Watson, and Roxane Patent Litigations

1. Endo settles with Actavis

142. Less than a year after suing Actavis, on or about February 20, 2009, Endo settled all of the Actavis Patent Litigation (the "Actavis Settlement"). On February 25, 2009, the Actavis Patent Litigation was dismissed with prejudice.

143. As discussed above, Actavis was the first-filer on the 7.5 and 15 mg strengths of Opana ER, which are primarily used to taper patients on and off Opana ER. At all relevant times, these two strengths have never constituted more than 10% of Endo's Opana ER sales.

144. Under the terms of the Actavis Settlement, Actavis agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Actavis a license permitting the production and sale of generic Opana ER 7.5 and 15 mg tablets by the earlier of July 15, 2011, or the date on which any third party commences commercial sales of a generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010. Endo also granted Actavis a license to produce and market other strengths of generic Opana ER on the earlier of July 15, 2011 or the date on which any third party commences commercial sales of a generic form of the drug. Endo's subsequent Exclusion Payment Agreement with Impax rendered that portion of the agreement with Actavis illusory as Endo and Impax used Impax's first-filer status to prevent any other generics from launching those strengths earlier than July 2013 (180 days after Impax's belated January 2013 launch).

145. But for the Exclusion Payment Agreement between Endo and Impax, Actavis would have been able to launch its generic versions of the 5, 10, 20 30, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 (and July 2010 for the 30 mg). However, due to the Exclusion Payment Agreement, Actavis did not launch those strengths until mid-2013. Additionally, in March 2011, just before Actavis was able to launch the 7.5 and 15 mg strengths of Opana ER under the terms of the Actavis Agreement, Endo discontinued selling those strengths, impeding Actavis' entry and greatly reducing the sales Actavis otherwise would have made upon launching the first generic versions of the 7.5 and 15 mg strengths.

2. Endo settles the Barr, Sandoz, Watson, and Roxane patent litigations

146. On or about April 12, 2010, Endo settled all of the Barr Patent Litigation relating to Opana ER. Under the terms of the settlement, Barr agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Barr a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date became illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Barr could not launch its generic until 180 days after Impax launched in January 2013.

147. The Sandoz litigation had proceeded to a bench trial that commenced on June 3, 2010 before Judge Hayden. On or about June 8, 2010 (the same time as the Endo/Impax Exclusion Payment Agreement and prior to Judge Hayden issuing any dispositive rulings in the bench trial), Endo settled all of the Sandoz Patent Litigation relating to Opana ER. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Sandoz a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain

circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Sandoz could not launch its generic until 180 days after Impax launched in January 2013.

148. On or about October 4, 2010, Endo settled all of the Watson Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Watson a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Watson could not launch its generic until 180 days after Impax launched in January 2013.

149. On or about May 4, 2011, Endo settled all of the Roxane Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Roxane a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Roxane could not launch its generic until 180 days after Impax launched in January 2013.

150. Notwithstanding agreements for nominal entry dates in 2012, Barr, Sandoz, Watson, and Roxane were not able to sell a generic Opana ER product until 180 days after Impax's generic launch. As such, the real launch date for Barr, Sandoz, Watson, and Roxane generics could not be before July 2013, a delay that Endo secured through Endo's Exclusion Payment Agreement with Impax.

151. The importance of the Barr, Sandoz, Watson, and Roxane settlements for Endo was that they prevented a court ruling that could threaten the validity of the '456 and '933

patents and move up the trigger date for Impax's 180-day exclusivity and the launch of generic OpanaER.

D. As a Result of the Delay Endo Bought with the Illegal Exclusion Payment Agreement with Impax, Endo was Able to Switch the Market from Opana ER to Opana ER CRF, Greatly Reducing the Sales Available to the Generic for Opana ER When it Eventually and Belatedly Entered the Market

152. Endo knew that in 2013 when generics for Opana ER were finally able to come onto the market there would be "substantial share erosion" for brand Opana ER and thus Endo had set about "working on multiple levels to combat that."

153. Accordingly, shortly after buying off Impax and illegally securing an additional two and a half years of its Opana ER monopoly, Endo set about switching the market from Opana ER to Opana ER CRF because generic Opana ER would not be automatically substitutable for Opana ER CRF.

154. The FDA approved Endo's supplemental NDA for Opana ER CRF on December 9, 2011. In approving Opana ER CRF, the FDA did not address any potential competitive effects associated with the approval of the Opana ER CRF formulation or Endo's efforts to switch the market from Opana ER to Opana ER CRF. To accomplish the switch between Opana ER and Opana ER CRF, Endo discontinued the sale of Opana ER, requiring physicians desiring to prescribe extended release oxymorphone hydrochloride to prescribe Opana ER CRF instead. The FDA found that Opana ER CRF is not safer than Opana ER and may in fact be more dangerous than Opana ER. Thus, if generic Opana ER had launched before Opana ER CRF (as would have occurred but for the Exclusion Payment Agreement), the generic would have quickly captured the vast bulk of brand Opana ER sales, and the subsequent launch of Opana ER CRF (assuming Endo still decided to launch the CRF formulation) would have had little effect on the sales of generic Opana ER.

155. But for the illegal Exclusion Payment Agreement, Endo's launch of Opana ER CRF would have occurred (if it occurred at all) long after generics had entered the market on or shortly after June 14, 2010 and captured the vast majority of the United States extended release oxymorphone hydrochloride market. As a result, most, if not all, of the prescriptions that are now being filled with Opana ER CRF instead would have been filled with generic extended release oxymorphone hydrochloride.

156. Thus, due to the Exclusion Payment Agreement and the effects flowing from the delayed entry of Impax, Actavis, Barr, Sandoz, Watson, and Roxane, Plaintiffs continue to suffer overcharges even after generic entry.

VI. INTERSTATE COMMERCE

157. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. MARKET POWER AND MARKET DEFINITION

158. At all relevant times, Endo had market power with respect to extended-release oxymorphone hydrochloride because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales.

159. A small but significant, non-transitory price increase above the competitive level for Opana ER by Endo would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

160. At competitive price levels, Opana ER does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Opana ER.

161. The existence of other products designed to treat similar disorders has not significantly constrained Endo' pricing of Opana ER. At all relevant times, Endo' price for Opana ER has been substantially above its marginal cost of production, and substantially above its marginal cost including marketing costs. Endo has never lowered the price of Opana ER in response to the pricing of other medications (or the launch of generic versions of those other medications).

162. Endo needed to control only Opana ER and its AB-rated generic equivalents, and no other products, in order to maintain the price of Opana ER profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Opana ER would render Endo unable to profitably maintain supracompetitive prices for Opana ER.

163. Endo knew that entry of a generic version of Opana ER would be a uniquely significant market event. The entry of other branded drugs in the same therapeutic class (or generic versions of those other brands) did not take substantial sales from Opana ER or cause Endo to lower its price. But Endo was aware that entry of generic Opana ER would immediately cause branded Opana ER to lose 80 to 90% of its unit sales.

164. At all relevant times, Endo has sold Opana ER at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

165. Endo had, and exercised, the power to exclude and restrict competition in the market for Opana ER and its AB-rated generic equivalents.

166. Endo, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

167. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Opana ER and its AB-rated generic equivalents. During the relevant time, Endo has been able to profitably maintain the price of extended-release niacin well above competitive levels.

168. The relevant geographic market is the United States and its territories.

169. Until the belated entry of generic Opana ER in early 2013, Endo's market share in the relevant market was 100%, implying a substantial amount of market power.

VIII. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS

170. But for the anticompetitive conduct alleged above, Opana ER would have been subject to AB-rated generic competition on or shortly after June 14, 2010. Endo would have launched an authorized generic version of Opana ER at that same time. Other generic manufacturers would have entered the market with additional generic versions of Opana ER thereafter.

171. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Opana ER from generic competition.

172. Defendants' anticompetitive conduct, which delayed and suppressed the introduction into the United States marketplace of generic versions of Opana ER, has caused Plaintiffs and/or their assignors to pay more than they would have paid for extended-release oxymorphone hydrochloride absent Defendants' illegal conduct.

173. But for Defendants' anticompetitive conduct, Plaintiffs and/or their assignors would have paid less for extended-release oxymorphone by: (a) substituting purchases of less-

expensive AB-rated generic Opana ER for their purchases of more-expensive branded Opana ER; and (b) purchasing generic Opana ER at lower prices sooner.

174. Plaintiffs and/or their assignors purchased substantial amounts of Opana ER. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for extended-release oxymorphone hydrochloride. Plaintiffs and/or their assignors paid prices for extended-release oxymorphone hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

175. As a consequence, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. Plaintiffs' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

176. Defendants' anticompetitive scheme threatens continuing loss and injury to Plaintiffs unless enjoined by this Court.

IX. CLAIMS FOR RELIEF

Claim I: Violation of 15 U.S.C. § 2 Monopolization (Asserted Against Endo)

177. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 176 above as though fully set forth herein. This claim is asserted against Endo.

178. At all relevant times, Endo possessed substantial market power (i.e., monopoly power) in the relevant market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

179. Through its overarching anticompetitive scheme, as alleged above, Endo willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct,

rather than by means of greater business acumen, and thereby injured Plaintiffs. Such conduct includes (a) entering into the unlawful Exclusion Payment Agreement with its generic competitor Impax; and (b) during the delay it purchased from Impax, switching the market from the existing legacy strengths of the drug to new strengths to prevent automatic generic substitution when generic versions of the legacy strengths finally became available. Endo's conduct was designed to delay and suppress generic competition to Opana ER and maintain Endo's monopoly power in the relevant market.

180. It was Endo's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

181. Endo's scheme substantially harmed competition in the relevant market.

182. There is and was no cognizable, non-pretextual procompetitive justification for Endo's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Endo were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

183. As a direct and proximate result of Endo's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim II: Violation of 15 U.S.C. § 2
Attempt to Monopolize
(Asserted Against Endo)

184. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 176 above as though fully set forth herein. This claim is asserted against Endo.

185. Endo, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Endo's conscious objective to control prices and/or to exclude competition in the relevant market.

186. The natural and probable consequence of Endo's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

187. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

188. As a direct and proximate result of Endo's illegal and monopolistic conduct, Plaintiffs and/or their assignors have suffered injury to their business and property.

Claim III: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against All Defendants)

189. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 176 above as though fully set forth herein. This claim is asserted against all Defendants.

190. On or about June 8, 2010, Endo, Penwest and Impax entered into the Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Endo agreed to make large and unjustified payments to Impax in exchange for Impax's agreement to delay bringing its generic version of Opana ER to market. The purpose and effect of this Agreement was to: (a) allocate to Endo 100% of the market for Opana ER and its generic equivalents in the United States; (b) delay and impair the sale of generic versions of Opana ER in the United States, thereby protecting Endo from unrestrained generic competition; (c) allocate to Impax 100% of the market for generic Opana ER in the United States for 180 days after Impax's belated launch of generic Opana ER; and (d) fix the price at which Plaintiffs purchased Opana ER and its generic equivalents at supracompetitive levels, both before Impax's launch and for 180 days thereafter.

191. The purpose and effect of the payments flowing from Endo to Impax was to delay and impair generic competition to Opana ER, and there is no legitimate, non-pretextual, precompetitive justification for the payments that outweighs their harmful effects.

192. The Exclusion Payment Agreement did have and was likely to have a substantially adverse effect on competition in the relevant market.

193. In the alternative, the Exclusion Payment Agreement was a horizontal market allocation agreement that divided the market temporally rather than geographically—Impax agreed not to compete with Endo from June 2010 until early 2013, and Endo agreed not to compete with Impax during Impax's 180 days of exclusivity. The Exclusion Payment Agreement was also a horizontal price-fixing agreement in which Endo agreed to sell Opana ER only at the higher branded price and not at the lower generic price during Impax's 180 days of exclusivity. As a horizontal market-allocation and price-fixing agreement, the Exclusion Payment Agreement was unlawful *per se*.

194. At all relevant times, Endo possessed market power in the relevant market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

195. The goal, purpose and/or effect of the Exclusion Payment Agreements was to prevent and/or delay generic competition to Opana ER and enable Endo to continue charging supracompetitive prices for Opana ER without a substantial loss of sales. By means of those Agreements, Defendants shared the supracompetitive profits that their unlawful conspiracy made possible.

196. As a direct and proximate result of Defendants' unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XI. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: March 26, 2015

Respectfully submitted,

/s/ David Lesht
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